1.4 510(k) Summary of Safety and Effectiveness

K102859

OCT 2 8 2011

Submitted by:	Herbert Crane Director, Global Regulatory Affairs
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Date of Submission:	August 5, 2011
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Product Code:	NHA
Trade or Proprietary or Model Name:	NobelActive 3.0 GoldAdapt Abutment
Legally Marketed Devices:	Nobel Biocare – NobelActive 3.0 (K102436) Nobel Biocare – NobelActive GoldAdapt Abutment (K083100)

Device Description:
The NobelActive 3.0 GoldAdapt Abutment is an abutment intended to be used with the Nobel Biocare NobelActive 3.0 implant system. The abutments are made of a gold alloy.

Indications for Use:
The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

Non-Clinical Testing:
Non-clinical test data was used to support the decision of substantial equivalence. Non-clinical testing consisted of performance of fatigue testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The testing indicates that the device is strong enough to withstand the anticipated forces.

Clinical Testing:
No clinical testing was performed. Non-clinical test data was used to support the decision of safety and effectiveness.

Conclusions:
The testing indicates that the abutments are substantially equivalent to the identified predicates.

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Substantial Equivalence Comparison to Predicate Devices

CHARACTERISTIC	PREDICATE	PREDICATE	CANDIDATE
	NobelActive GoldAdapt Abutment (K083100)	NobelActive 3.0 (K102436)	**NobelActive 3.0 GoldAdapt Abutment**
Trade Name	NobelActive	NobelActive	**NobelActive**
Anatomical Site	Oral Cavity	Oral Cavity	**Oral Cavity**
Abutment Material	Gold Alloy	Titanium Vanadium Alloy	**Gold Alloy**
Abutment angulation	0 deg	0 deg	**0 deg**
Implant/Abutment Connection	Internal Hex	Internal Hex	**Internal Hex**
Indications for Use	Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.	The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.	**The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 8 2011

Nobel Biocare AB
C/O Mr. Herbert Crane
Director, Global Regulatory Affairs
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K112259
Trade/Device Name: NobelActvie 3.0 GoldAdapt Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 27, 2011
Received: September 28, 2011

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use

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510(k) Number (if known):

Device Name: **NobelActive 3.0 GoldAdapt Abutment**

Indications For Use:

The NobelActive 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112259